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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,531	03/29/2001	Eugenia Wang	UNLV 1010	3924

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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 04/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,531	WANG, EUGENIA	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-29 and 34-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-29 and 34-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1634

DETAILED ACTION

1. Applicant's election of Group III (**Claim(s) 21-29 and 34-40**) without traverse in the paper filed 29 JAN 03 is acknowledged. In addition, the cancellation of Claims 1-20, 30-33 and 41 is acknowledged. The restriction requirement has been reconsidered, is deemed proper and is therefore, herein made **FINAL**. An action on **Claim(s) 21-29 and 34-40** follows.

SEQUENCE RULES

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

35 USC § 112- 2ND PARAGRAPH

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

4. **Claim(s) 21-29, 34-40** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is indefinite because there is no nexus between the preamble and the claim steps. Claim 21 in its preamble direct to a method which is to accomplish a particular goal. However, none of the claim steps states that this goal is accomplished. For clarity, claimed methods should recite

Art Unit: 1634

that the purpose of the method has been attained (i.e. provide a nexus between the preamble and the claim steps).

In **Claim 21** the phrase "interacting with a gene binding to the regulatory sequence" on lines 4, 7 and 13 is nonsequitur. It is unclear what is intended. Please clarify.

Also, in **Claim 21** it is unclear to what the phrase "having a length between 480 and 700 base pair length and a melting point between 75 and 85°C" refers. Please clarify.

In **Claim 22** the phrase "genes interacting with genes binding to the regulatory sequence" on lines 2-3 is nonsequitur. It is unclear what is intended. Please clarify.

In **Claim 26** the phrase "genes interacting with genes binding to the regulatory sequence" on line 4 is nonsequitur. It is unclear what is intended. Please clarify.

Claim 34 is indefinite because there is no nexus between the preamble and the claim steps. Claim 34 in its preamble direct to a method which is to accomplish a particular goal. However, none of the claim steps states that this goal is accomplished. For clarity, claimed methods should recite that the purpose of the method has been attained (i.e. provide a nexus between the preamble and the claim steps).

35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

Claim Rejections under 35 USC § 102

- 6.** Claim(s) 22-23, 25-29, 34-38 is/are rejected under 35 U.S.C. 102(b) as being anticipated by DeRisi et al. (DEC 1996).

DeRisi et al. teach a method of screening for differential expression of one or more regulatory genes or genes interacting with genes binding to the regulatory sequence as recited in Claim 22-23, 25-29, 34-38.

- 7.** Claim(s) 22, 24-28 and 34-37 is/are rejected under 35 U.S.C. 102(e) as being anticipated by Lockhart et al. [US 6,524,800 (FEB 2003)].

Lockhart et al. teach a method of screening for differential expression of one or more regulatory genes or genes interacting with genes binding to the regulatory sequence as recited in Claim 22, 24-28, and 34-37.

35 USC § 103

- 8.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

CLAIM REJECTIONS UNDER 35 USC § 103

- 9.** Claim(s) 39-40 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over DeRisi et al. (DEC 1996).

DeRisi et al. teach a method of screening for differential expression of one or more regulatory genes or genes interacting with genes binding to the regulatory sequence as recited in Claim 39-40 except these authors do not explicitly teach an embodiment wherein the disease/cancer is one of

Art Unit: 1634

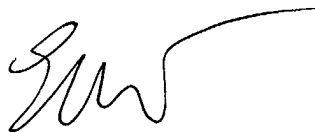
those listed in Claims 39-40. However, as all of the diseases /cancers were well known at the time of the invention, it would have been, absent an unexpected result, *prima facie* obvious to one of ordinary skill in the art at the time of the invention to analyze the gene expression patterns of those genes present on the microarray taught by DeRisi et al. and affected by the diseases/cancers recited in Claims 39-40. The ordinary artisan would have been motivated to analyze the gene expression patterns of those diseases/cancers recited in Claims 39-40 in order to identify previously unrecognized alterations in the expression of specific genes which would have provided leads for further investigation.

CONCLUSION

10. Claim(s) 21-29 and 34-40 is/are rejected and/or objected to for the reason(s) set forth above.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



Ethan Whisenant, Ph.D.
Primary Examiner